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*APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,714	11/26/2001	Timothy Elliot Trigg	47-163	4005

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,714	TRIGG ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-30* is/are pending in the application.

4a) Of the above claim(s) *23-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 17-22 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that "a restriction requirement was not made in the parent application, now granted as U.S. Patent 6,337,318, and that the scope of all the claims of the present application were fully searched by the Examiner of the parent application". Applicant's arguments are not found persuasive since the fact that the other Examiner chose to search all the separate inventions in the previous application, is not binding on the present application. Furthermore, Applicant has not addressed or overcome the substance of the restriction requirement of record for the reasons of record. Applicant is reminded that a search of Groups I-IV would be extensive while not being coextensive, and that a search of the extensive biotechnology databases would be required for each of Groups I-IV. The present application is a separate application from the former application. Therefore, Groups II-IV, claims 23-30, are withdrawn from consideration as being drawn to non-elected inventions. Group I, claims 17-30, as drawn to elected species of Group I, are examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Rejections

35 U.S.C. § 112, 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention, and claims 17-22, are drawn to a pharmaceutical composition comprising any GnRH agonist, which may be a peptide agonist, and lecithin and stearin (both non-crystalline form), all of which are contained in the composition in various percentages (% (w/w)). Specifically elected are 5% of the GnRH peptide agonist, 1% lecithin, and the balance stearin.

One of skill in the art would not recognize from the disclosure that Applicant was in possession of any GnRH agonist or any GnRH peptide agonist. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Specification page 6 describes that "[p]ersons skilled in the art will be well aware of GnRH agonists or analogues which can be usefully employed in the

present invention", but only specifically describes 11 GnRH agonist examples, all peptides, of which 7 of these 11 are described as preferred; but only in fact describes testing of 5 of the 11 GnRH agonists as pharmaceutical treatment capability: deslorelin, goserelin, leuprolide, buserelin, and triptorelin (of which the elected "eulexin" was not one of the those preferred or tested). And since claim 17 negatively claims deslorelin for omission from the invention, only 4 of the possible 10 remaining GnRH peptide agonists, described in the specification, have been subjected to pharmaceutical treatment experimentation (all 4 of which were patented, with 3 other GnRH peptide agonists, under the parent application, now issued as US 6337318 B1). The claims have not specifically recited any GnRH agonists or GnRH peptide agonists for use in the invention.

Thus, the specification only describes 4 GnRH peptide agonists (other than deslorelin) that have been tested for use as a pharmaceutical composition, while no specific GnRH agonists or GnRH peptide agonists have been specifically claimed. Furthermore, although Applicant's elected GnRH agonist, "eulexin", a peptide, was described, it was not tested as a pharmaceutical composition. With the substantial variability among the 4 GnRH peptide agonists tested in the pharmaceutical composition, and with potential inflammatory risks and other unknown physiological effects, as shown in Figures 5-8 and 13-14 and on pages 11-12 of the application, it is not clear as to whether any GnRH agonist or GnRH peptide agonist would be tolerated in vivo as part of the pharmaceutical composition. One of skill in the art would not recognize from the disclosure that Applicant was in possession of the genus; namely any GnRH agonist, or the species, any GnRH peptide agonist, for use in the pharmaceutical composition.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

35 U.S.C. § 112, 1st Scope of Enablement

Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 5 GnRH peptide agonists (really 4 since deslorelin has been negatively claimed in claim 1, leaving only goserelin, leuprolide, buserelin, and triptorelin), does not reasonably provide enablement for any GnRH agonist or GnRH peptide agonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants have reasonably taught and/or demonstrated 5 GnRH peptide agonists, 4 of which have not been negatively claimed. However, broad claim 17 necessarily encompasses any GnRH peptide or GnRH peptide agonist. Since peptides are the only GnRH agonists described, only such peptides can be analyzed. As shown by Applicant's Figures 5-8 and 13-14 and pages 11-12, the effect on the recipient due to the GnRH peptide agonist selected and length of implantation, of the pharmaceutical composition, can have inflammatory potential on the tissue. Therefore, it cannot be determined whether any GnRH agonist or GnRH peptide agonist, would result in inflammatory or other reaction, without proper testing.

Based on the highly unpredictable and complex nature of determining pharmaceutical tolerance and long-term effects, and Applicant's own examples as provided in the specification and Figures, that different inflammatory and other effects on the tissue may be impacted by the agent selected and length of implantation, determining which GnRH agonists and GnRH peptide agonists will function as a pharmaceutical in the present composition, without unwanted effects,

would require undue experimentation without a reasonable expectation of success by one of skill in the art.

35 U.S.C. § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17, it is unclear what is contemplated as "at least one GnRH agonist"? The claim's only arguable indication of what GnRH agonists are contemplated by the invention is through the negative claiming "other than deslorelin". The specification describes 11 specific GnRH peptide agonists (other than deslorelin) (column 4, lines 29-51); of which 7 of these are listed as preferred GnRH peptide agonists (column 4, lines 52-66; column 5, lines 1-18). In response to the election of species requirement, eulexin (5% on an active basis) was elected as the GnRH agonist. However, eulexin has not been claimed, nor have any other specific GnRH agonists.

In overcoming the above rejection, it is strongly suggested that Applicant distinctly claim those GnRH agonists contemplated for use in the invention (consistent with what is fully described within the specification as capable of use as a pharmaceutical implant and method of treatment). [See US application No: 09/242,635 (now US 6337318 B1); where the claims were amended to incorporate original claim 7 (drawn to the 7 preferred GnRH agonists, of the 11

described in that application, other than deslorelin) into claim 1; in order to distinctly claim those GnRH agonists contemplated by invention].

35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US 5573781).

Brown et al. teach a pharmaceutical semi-solid comprising a cytostatic agent (including flutamide (column 4, lines 34 and 61; Schering-Plough Corp. manufacturers flutamide under the trade name "eulexin", as shown in Labri (US 5372996, column 10, lines 45-49)), wherein the cytostatic agent ("eulexin") is an amount to slow the growth of said cellular proliferative disease (claim 27); and a carrier composition comprising a fatty acid matrix of 2 to 95 % (w/w) [i.e. leaving a 5% remainder as "eulexin"] (comprising "any suitable physiologically acceptable lipid matrix material . . . either a single fatty acid ester or a mixture of fatty acid esters" (column 2 lines 54-55 and 59-60), such as tristearin (column 3, line 62 and column 4, line 6; tristearin is another name for "stearin", as shown in Hawley (Hawley's Condensed Chemical Dictionary, Thirteenth Edition, 1997, page 1046), and also "compounds affecting cellular permeability may be employed, such as . . . phospholipids" (column 5, lines 50-52 and column 6, lines 4-5; phospholipids are another name for "lecithin", as shown in Hawley page 666)). [Brown et al. also teach the pharmaceutical semi-solid being used for the treatment of cellular proliferative

diseases (such as "prostate cancer") and the like in humans and domestic animals (column 8, lines 26-33 and claims 22-36).]

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply routine optimization using the teachings of Brown et al. to arrive at the % (w/w)'s of eulexin (elected 5%, or 2-15%, 5-10%, 5%), "lecithin" (elected 1%, 0.5-3.5%, 0.5-1.5%), and "stearin" (elected balance stearin, 89-94%, 94%) as the pharmaceutical solid of Applicant, since Brown et al. used the same compounds in a pharmaceutical semi-solid for treatment of cellular proliferation diseases; wherein the fatty acid matrix primarily comprises any suitable acceptable lipid matrix material, such as "stearin" from 2-95%, along with "eulexin" and "lecithin"; and "eulexin" in "an amount to slow the growth of said cellular proliferative disease" (i.e. routine optimization, claim 27).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting - Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 17-30 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of prior U.S. Patent No. 6337318 B1 (Trigg et al.). This is a double patenting rejection.

Trigg et al. teach the same products with GnRH peptide agonists and methods of using GnRH peptide agonists, including percentages, as the present application (claims 1-10). US 6337318 B1 specifically claims 7 GnRH agonists, "selected from the group consisting of goserelin, leuprorelin, triptorelin, meterelin, buserelin, histrelin, nafarelin, and combinations thereof" (claim 1; species of Applicant's claim 1 GnRH agonists and claim 7 GnRH peptide agonists).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
June 12, 2003

MICHAEL [illegible]
PRIMARY EXAMINER